

Appl. No. : 10/824,933  
Filed : April 15, 2004

### REMARKS

In response to the Office Action mailed October 9, 2007, Applicant respectfully requests that the Examiner reconsider the above-captioned patent application in view of the foregoing amendments and the following comments. As a result of the amendments set forth above, Claims 1-20, 24, 31-37, 40-44, and 46-51 remain pending. Claims 1, 4, 9-14, 16, 17, 31, 42, and 44 have been amended. Claims 49-51 have been added. Claims 21-23, 25-30, 38-39, and 45 have been cancelled.

#### Claim 1 - Sterling (102(c))

Claim 1, as amended, recites, among other limitations, an identifying compound that is:

*disposed within or on at least one of the parallel faces of the sample chamber, the sample element configured such that the identifying compound does not intermingle with the sample fluid, the identifying compound also disposed in the optical path such that the electromagnetic radiation passes through the identifying compound as the radiation propagates through the sample chamber*  
....

The Examiner refers to the gold coating described by Sterling as disclosing an identifying compound within the scope of the claim. However, the gold coating of Sterling is not disposed within or on at least one of the parallel faces of the sample chamber, as recited in amended Claim 1. The polished gold coating taught in Sterling is a reflective coating on an inner surface of an optical mixer 20 and a collimator 22. Sterling, [0092]). These surfaces are not part of a sample chamber, as claimed, but are instead part of an optical system that pre-conditions radiation before it encounters the sample (S in Figure 1) or even the window adjacent the sample (12 in Figure 1). Moreover, the embodiment of Sterling relied upon by the Examiner does not allow radiation to pass "through the identifying compound as the radiation propagates through the sample chamber" because the surfaces with gold coating in Sterling are described as being "highly reflective and minimally absorptive." (Sterling, [0092]). For at least these reasons, Sterling does not anticipate amended Claim 1.

Claims 2-8 depend from Claim 1, and are thus patentable for at least the same reasons discussed with respect to Claim 1. These claims also recite additional features that make them patentable over Sterling.

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Claim 9 - Jina (102(b)):

Claim 9 has been amended to recite an identification key that comprises "an optical property of the sample element." Jina teaches a sample element having a particular shape of its tip, and also having an "electrically conductive surface." (Col. 12:58). Neither of these is an optical property as required by amended Claim 9. Even in the embodiment described with respect to Figures 9-12 (Col. 13:46-65) with the "light detectable means 92," it is the shape of the sample element that enables the "detection means 106" to determine whether the sample element has been fully inserted. Thus, Jina teaches using the shape of a cuvette, and not an "optical property of the sample element." Moreover, in addition to not teaching a "identification key" that comprises "an optical property of the sample element," Jina does not teach "an identification key in the optical path for determining analyte concentration" because the "light detectable means 92" taught by Jina is offset optically from the reaction zone 93 and the optics 114.

Claims 10-12, 41, and 47 depend from Claim 9, and are thus patentable for at least the same reasons discussed with respect to Claim 9.

Claim 31 - Jina (102(b))

Claim 31 has been amended to recite, among other limitations, that "qualifying the sample element" comprises "optically determining a characteristic of the portion of the sample element in the optical path." Jina teaches a sample element having a particular shape of its tip, and also having an "electrically conductive surface." Neither of these can be used for qualifying the sample element by "optically determining a characteristic of the portion of the sample element in the optical path," as claimed. The "optics 84" taught by Jina "for reading the reaction zone 63" (Jina Col. 12:67), are not for "qualifying the sample element," as recited in amended Claim 31. The embodiment described with respect to Figures 9-12 (Col. 13:46-65) has a "light detectable means 92" that can be detected by "detection means 106" to determine whether the sample element has been fully inserted. However, neither the detection means nor the detectable means are described as being used for analyte concentration determination. Thus, this description in Jina does not anticipate amended Claim 31, which states that "the optical path" referred to is also for "determining analyte concentration." Claims 32-37 and 40 depend from Claim 31, and are patentable for at least the same reasons discussed with respect to Claim 31.

Claim 42 – Jina (102(b))

Claim 42 has been amended to recite, among other limitations, that the sample element is "optically" qualified by "emitting radiation along an optical path through the sample element." This is different from Jina, as explained above with respect to Claims 9 and 31, because Jina does not teach use of optics for qualifying a sample element as claimed. Claim 42, as amended, also clarifies that, in a later step that is conditional on the earlier qualification, analysis of the material sample is accomplished "by emitting radiation along the same optical path used to qualify the sample element." The passage referred to in the Office Action teaches that the "optics 84" taught by Jina are "for reading the reaction zone 63." The angled tip and the electrical contacts taught by Jina do not involve emitting radiation along an optical path as recited in Claim 42. There is not suggestion in Jina that "light detectable means 92" and the "detection means 106" operate along an optical path that is the same as that used to analyze an optical property of a material sample. Thus, Jina does not teach using the same optical path for qualification and analysis. For at least these reasons, Jina does not anticipate amended Claim 42.

Claim 14 – Douglas (102(b))

Claim 14 has been amended to recite, among other limitations, that the claimed sample chamber is "reagentless." Douglas does not teach a time when a sample element is reagentless, as suggested in the Office Action with respect to Claim 45. As explained throughout the summary of the invention and with respect to each embodiment (Col. 3:59, 64-66; Col. 4: 41-42; Col. 5:5:23, 33-35; Col. 6: 26-29, 42-45), reagent is contained within a "porous matrix" that has a "dry chemistry system." The porous matrix is provided with the test strip. Thus, Douglas does not teach, as stated in the Office Action, a "period before introducing" reagent into a chamber. (Office Action, p. 6). Indeed, Douglas specifically teaches a reagent-based analysis process in the following passages cited in the Office Action: Col. 11:5-8; 12:54-13:9; Col. 15:39-62; Col. 23:49-67. Moreover, the passages cited in the Office Action are not relevant to the claim because they do not teach an identification key that is located in an optical path for analyte measurement. The machine readable coding of Col. 17:52-55 and Col. 16:2-15 may be optically readable, but it is not in an optical path for analyte measurement because the coding itself (see, e.g., the bar-code illustrated in Figures 1 and 2) would render inoperable an analyte measurement by blocking the optical path for analysis of the sample itself. Nor are the protrusions of Col.

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19:10-28 in an optical path for analyte measurement. The passages cited in the Office Action in relation to "a qualification state of the sample element" (Col. 11:5-8; Col. 12:54-13:9; Col. 15:39-62; Col. 23:49-67) do not relate to a qualification state of a "sample element," but instead relate to analysis of the sample substance itself using reagents.

Claims 15-18 and 48 depend from Claim 14, and are patentable for at least the same reasons discussed with respect to Claim 14. Claim 16 has been amended to clarify that "the identification key comprises a compound that is distinct from the sample." Additionally, Claim 17 has been amended to clarify that "the qualifying optical absorbance feature has an optical signature that is adjacent to or overlapping an optical signature of an absorbance feature of an analyte detectable in the sample fluid," and that this adjacent or overlapping nature is "determined when a sensor is used to generate a scan of absorbed radiation." The cited passages of Douglas does not teach anything about the relationship between the results of a scan of the sample fluid itself to a scan of the "absorbance feature," and a bar-code disclosure is irrelevant to this claim. Claims 21 and 45, which depended from Claim 14, have been cancelled.

Claim 1 – Sterling in view of Hillman (103(a))

Claim 1 is patentable over Sterling in view of Hillman for the same reasons provided above with respect to Sterling alone. Additionally, the passages of Hillman cited in the office action (Col. 2:50-55; Col. 3:65-4:1; Col. 5: 67-6:5; Col. 6:60-67) do not support the assertion in the office action. Whereas these passages purport to provide support for the teaching that "use of coating to qualify a sample element for use with a particular analyte detection system is known in the art," in fact, none of these passages discuss sample element qualification. The only passage that even alludes to a coating does so obliquely:

*The reagents may be present either diffusively or non-diffusively bound to the surface of the device, that is, adhered, absorbed, adsorbed or covalently-linked, so that the reagent may become dissolved in the fluid or may remain fixed to the surface. (Col. 6:60-64).*

The substance "bound to the surface of the device" is not for qualifying the sample element but is a "reagent," for reacting with the sample itself. This directly contradicts of Claim 1, which states: "the sample chamber [is] reagentless." Thus, not only do these passages not support the assertion (because they do not relate to sample element qualification), they also teach the opposite of the "reagentless" recitation in amended Claim 1.

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Claim 13 – Jina in view of Douglas (103(a))

Dependent Claim 13 is patentable for at least the reasons given above with respect to Claim 9. Additionally, the passages in Douglas cited in the Office Action (Col. 6:45-53; Col. 16:7-15) merely mention the word "calibration" but do not provide any teaching relating to "a background optical absorbance spectrum of the optical path." Moreover, the "optical path" referred to in this claim is the one introduced in Claim 9: "optical path for determining analyte concentration." A bar code, as taught by Douglas (e.g., a pattern of black bars on a sticker) would block or greatly attenuate transmission of the radiation, frustrating the purpose of an analyte detection system, if it were placed directly in an optical path for determining analyte concentration. Thus, the teachings of Douglas cited in the Office Action do not disclose or suggest the limitations of Claim 13. Claims 38 and 39, which were dependent on Claim 13, are cancelled.

Claims 19-20, 24 – Douglas in view of Sterling (103(a))

Claims 19, 20 and 24 depend from Claim 14. Thus, Claims 19 and 20 are patentable over the Douglas and Sterling reference for the same reasons given above with respect to Claim 14. Moreover, as clarified by amended Claim 16, "the identification key comprises distinct from the sample." Claims 19 and 20 also depend from Claim 16. Accordingly, the passages cited in the Office Action are not relevant because they teach optical absorbance features of analytes that are in the sample. In contrast, the claimed "qualifying optical absorbance feature" is distinct from the sample. Thus, Claims 19 and 20 are patentable over the combination of the Douglas and Sterling references. Claims 25-26, which depended from Claim 14, have been cancelled.

Claims 22, 23 and 27-30 – Douglas in view of Sterling and Jina (103(a))

Claims 22, 23, and 27-30 have been cancelled.

Conclusion

For the foregoing reasons, it is respectfully submitted that the rejections set forth in the outstanding Office Action are inapplicable to the present claims. Accordingly, issuance of a Notice of Allowance is requested.

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Applicant respectfully traverses each of the Examiner's rejections and each of the Examiner's assertions regarding what the prior art shows or teaches. Although amendments, deletions and cancellations have been made, no acquiescence or estoppel is or should be implied thereby. Rather, the amendments, deletions and cancellations are made only to expedite prosecution of the present application, and without prejudice to presentation or assertion, in the future, of claims on the subject matter affected thereby. Any arguments in support of patentability and based on a portion of a claim should not be taken as founding patentability solely on the portion in question; rather, it is the combination of features or acts recited in a claim which distinguishes it over the prior art.


The undersigned has made a good faith effort to respond to all of the rejections in the case and to place the claims in condition for immediate allowance. Nevertheless, if any undeveloped issues remain or if any issues require clarification, the Examiner is respectfully requested to call Applicant's attorney, Andrew M. Douglas, at (949) 760-0404 to resolve such issue(s) promptly.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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